Intraosseous Basivertebral Nerve Ablation Procedure (Intracept®)

Policy MP-068

Origination Date: 05/25/2021

Reviewed/Revised Date: 01/23/2026

Next Review Date: 01/23/2027

Current Effective Date: 02/23/2026

Disclaimer:

1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial, CHIP, Healthy U (Medicaid) and Health Choice Utah (Medicaid) plans. Refer to the "Policy" section for more information.
3. Services requiring prior-authorization may not be covered, if prior-authorization is not obtained.
4. This Medical Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan, and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.

Description:

Chronic low back pain (CLBP) is defined as persistent pain in the lumbar region, which lasts for more than 12 weeks. CLBP has many different causes. One suggested cause is vertebrogenic CLBP, which is thought to be associated with degeneration of the vertebral body or vertebral body endplates, which results in inflammation. The inflammatory response is perceived by the basivertebral nerve, a sensory nerve that enters the posterior vertebral body and branches out to the superior and inferior endplates. Pain signals are then transmitted to the central nervous system, causing vertebrogenic pain.

Basivertebral nerve ablation (BVNA), such as with the Intracept® System (Relievant Medsystems Inc.), is intended to relieve CLBP thought to be due to vertebrogenic causes by inhibiting the transmission of pain signals.

The Intracept® Procedure is a minimally invasive outpatient procedure that targets the basivertebral nerve (BVN) for relief of CLBP caused by vertebrogenic pain between L3 and S1. It consists of the Intracept Introducer Cannula, the Intracept Curved Cannula, the Intracept Radiofrequency Probe, and the Intracept Radiofrequency Generator. According to Relievant Medsystems Inc., the cannula is inserted via minimally invasive procedure under fluoroscopic guidance through the pedicle using a transpedicular approach. The procedure is performed under at least moderate conscious sedation. Fluoroscopic imaging is utilized to guide

transpedicular positioning of the intervertebral instruments. After reaching the location of the BVN trunk a flexible bipolar radiofrequency (RF) probe is inserted and then connected to a RF generator to heat the tip to 75-85 C for 7-15 minutes. This energy creates a 0.9-1.2 cm diameter spherical ablation zone. The procedure is repeated at each additional vertebral body identified pre-operatively.

Policy Statement and Criteria

1. Commercial Plans/CHIP

U of U Health Plans does not cover intraosseous radiofrequency basivertebral nerve ablation (Intracept® procedure) as it is considered experimental, investigational, or unproven

2. Medicaid Plans

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website at: https://medicaid.utah.gov/utah-medicaid-official-publications/ or the Utah Medicaid code Look-Up tool

Clinical Rationale

Radiofrequency ablation (RFA) of intraosseous nerves is an emerging minimally invasive technique for the management of chronic low back pain (CLBP). The procedure targets the basivertebral nerve (BVN), which is believed to transmit pain signals from the vertebral body to the central nervous system. Interrupting this pathway via RFA is hypothesized to relieve vertebrogenic pain originating from within the vertebral body. The INTRACEPT® System (Relievant MedSystems, Inc., Redwood City, CA) was cleared by the U.S. Food and Drug Administration (FDA) through the 510(k) process in 2016 for use in patients with chronic lumbar pain persisting for at least six months despite conservative management. Eligible patients typically present with Type 1 or Type 2 Modic changes at one or more vertebral levels (L3–S1) as visualized on MRI.

Despite regulatory clearance, there remains limited independent, non–industry-sponsored evidence supporting the clinical effectiveness of basivertebral nerve RFA for vertebrogenic pain. The majority of randomized controlled trials (RCTs) and pivotal studies have been industry sponsored, as highlighted in recent systematic reviews and narrative summaries. This reliance on sponsor-funded research has raised questions regarding potential bias, external validity, and generalizability of findings.

Further complicating the evidence base, the underlying diagnostic rationale—namely, the association between Modic changes (MCs) and chronic low back pain—remains uncertain. Herlin et al. (2018) conducted a systematic review and meta-analysis of 31 observational studies examining the relationship between Modic changes and low back pain or disability. Their findings indicated that the association is inconsistent, generally weak, and characterized by significant heterogeneity and risk of bias. Although some studies reported positive correlations, many did not, and no consistent link was found between Modic changes and functional impairment. The authors concluded that MCs alone are unlikely to serve as a reliable biomarker for vertebrogenic pain or activity limitation.

However, some real-world cohort studies and independent prospective trials have been published that do not appear to be industry sponsored. A recent prospective real-world cohort study by McCormick et al. (2025) evaluated 60 patients and found that over half experienced clinically meaningful improvements in pain and function at 12 months post-BVNA.[2] Another prospective uncontrolled trial by De Vivo et al. (2021) in Italy, using a different radiofrequency system (not the Intracept device), also reported significant improvements in pain and disability at 12 months, with a 96.5% clinical success rate and no significant complications.[3] These studies provide supportive data but are limited by their single-arm, non-randomized designs and smaller sample sizes.

A double-blind, sham-controlled RCT by Fischgrund et al. (2019), sponsored by Relievant Medsystems, enrolled 147 patients. The study reported statistically significant improvements in Oswestry Disability Index (ODI), Visual Analog Scale (VAS), and SF-36 Physical Component Summary at all follow-up points through 2 years. At 2 years, mean improvements from baseline were 53.7% for ODI and 52.9% for VAS. Responder rates remained consistent: ODI ≥10-point improvement in 76.4% of patients, ODI ≥20-point improvement in 57.5%, and VAS ≥1.5 cm improvement in 70.2%.

RCT by Smuck etal(2021), also industry-sponsored, compared BVNA to standard care in 140 patients, showing at 12 months ODI reduction of 28.5 points, VAS reduction of 4.1 cm, ~69% achieving ≥50% pain reduction, and ~31% pain-free, with durability through 24 months.

Conger et al. (2022) conducted a systematic review and meta-analysis published in *Pain Medicine* that pooled data from six unique study populations (12 publications, 414 patients). They reported that approximately 65% of patients achieved at least 50% pain relief at six months, and similar results persisted at twelve months. Functional improvement was also notable, with 75% of patients showing a 15-point or greater improvement in Oswestry Disability Index (ODI). Despite these encouraging findings, the authors rated the evidence as moderate quality and emphasized the need for more rigorous trials to confirm long-term effectiveness and comparative benefit (Conger et al., 2022).
Schnapp et al. (2022) conducted a scoping review published in *Pain Physician* that examined twelve studies and concluded that while basivertebral nerve ablation shows promise as a targeted therapy for vertebrogenic chronic low back pain, the evidence base remains heterogeneous and

insufficient for broad adoption. The review noted reliance on Modic changes for patient selection, absence of head-to-head comparisons with other minimally invasive treatments, and limited long-term data. The authors called for high-quality randomized controlled trials to establish comparative effectiveness and durability (Schnapp et al., 2022).

Loan and Kieser (2021) performed a meta-analysis in the *Open Journal of Radiology* that included six studies, all of which were industry-sponsored. The analysis found significant improvements in pain, disability, and quality of life within the first three months, with indications of sustained benefit over time. However, the review highlighted major limitations, including lack of independent trials, small sample sizes, and potential bias due to uniform sponsorship. Safety appeared favorable, with only one compression fracture reported across studies (Loan & Kieser, 2021).

Michalik et al. (2021) provided a narrative review in *Pain Medicine* summarizing the current evidence and future directions for BVN ablation. The authors highlighted the neuroanatomical basis for targeting the basivertebral nerve and summarized randomized controlled trials showing improvements in pain and function. However, they noted that all existing studies are industry-sponsored, raising concerns about bias. The review stressed the need for independent trials, comparative effectiveness research, and long-term safety data to validate BVN ablation as a standard treatment option (Michalik et al., 2021).

De Vivo et al. (2021) reported findings from a prospective uncontrolled trial evaluating CT-guided basivertebral nerve ablation in 56 patients with vertebrogenic chronic low back pain. The study demonstrated significant reductions in pain and disability at 3 and 12 months, with clinical success achieved in over 96% of patients. Importantly, no complications were observed, and the authors emphasized the role of advanced imaging for patient selection. However, the lack of a control group and randomization limits the strength of these conclusions, and the absence of comparative data means these results should be interpreted cautiously (De Vivo et al., 2021).

A real-world prospective cohort (published 2025, mixed sponsorship) of 60 patients by McCormick et al. (2025) reported more modest outcomes: at 12 months, ODI decreased by 14 points, 52.8% achieved ≥30% ODI improvement, and 49.1% had ≥50% pain reduction. So, real-world data show that only about 50–55% of patients report clinically meaningful improvement at 12 months, meaning nearly half do not achieve significant benefit.

Additionally, independent study by De Vivo et al. (2021) reported outcomes in 36 patients undergoing BVNA, with mean ODI improvement of 23 points and VAS reduction of 4.4 cm at 12 months, and no major complications. All studies reported low serious adverse event rates (<0.3%), but real-world effectiveness appears lower than in controlled trials.

The Hayes Health Technology Assessment assigned a C rating to the Intracept basivertebral nerve ablation system, indicating low-quality or insufficient evidence to support its routine use. While Intracept therapy appears reasonably safe and demonstrates statistically and clinically significant improvements in pain and function compared to baseline and continued conservative care, the overall evidence base remains weak. Notably, limited data suggest the therapy does not

provide clinically meaningful benefit compared to sham procedures, and there are no comparative studies against other minimally invasive treatments for refractory vertebrogenic chronic low back pain. These gaps highlight uncertainty regarding long-term outcomes and comparative effectiveness. Until robust, high-quality trials confirm superiority over sham and alternative options, widespread adoption of Intracept cannot be justified.

Despite growing interest in basivertebral nerve ablation for chronic low back pain, regulatory and health technology bodies have not universally endorsed or prioritized this intervention. For example, NICE in the UK reviewed the procedure during its topic selection process and did not progress it to a full Health Technology Evaluation, citing insufficient evidence and uncertainty regarding clinical benefit and cost-effectiveness. This lack of endorsement reflects ongoing gaps in high-quality, long-term data and raises concerns about widespread adoption of the Intracept device without robust comparative evidence to support its safety, efficacy, and value within publicly funded health systems.

The Hayes Health Technology Assessment gave the Intracept basivertebral nerve ablation system a C rating, signaling that the current evidence is of low quality and insufficient to justify routine use. While available studies suggest the procedure is generally safe and can lead to meaningful improvements in pain and function compared to baseline and ongoing conservative care, the evidence remains limited. In particular, results indicate no clinically significant advantage over sham treatment, and there are no direct comparisons with other minimally invasive options for persistent vertebrogenic chronic low back pain. These gaps underscore the need for additional research to establish both the long-term outcomes and the comparative effectiveness of Intracept therapy.

According to the manufacturer, safety and effectiveness have not been established in patients with poor bone quality (e.g., osteoporosis), severe cardiac or pulmonary compromise, active infection, or those with implantable pulse generators. Contraindications also include pregnancy, bleeding disorders, and cases where neurogenic claudication or radiculopathy are the primary symptoms.

Across available literature, basivertebral nerve ablation using the Intracept device demonstrates short-term improvements in pain and function for selected patients. However, the evidence base is limited by industry sponsorship, lack of independent trials, absence of head-to-head comparisons, and insufficient long-term data. While early results suggest safety and feasibility, these gaps raise concerns about bias and generalizability. Until robust, high-quality randomized controlled trials confirm comparative effectiveness, durability, and cost-effectiveness, routine adoption of Intracept cannot be recommended.

Applicable Coding

CPT Codes

64628 Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; first 2 vertebral bodies, lumbar or sacral

64629 Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; each additional vertebral body, lumbar or sacral (List separately in addition to code for primary procedure)

HCPCS Codes

No applicable codes

ICD-10 Codes

M47.816 Spondylosis without myelopathy or radiculopathy, lumbar region

M47.817 Spondylosis without myelopathy or radiculopathy, lumbosacral region

M51.36 Other intervertebral disc degeneration, lumbar

M51.37 Other intervertebral disc degeneration, lumbosacral

M54.50 Low back pain

M54.51 Vertebrogenic low back pain

ICD-10 Procedure Codes

Use of the following codes when specified as intraosseous basivertebral nerve ablation:

015B3ZZ Destruction of Lumbar Nerve, Percutaneous Approach

015B4ZZ Destruction of Lumbar Nerve, Percutaneous Endoscopic Approach

References:

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10. Smuck M, Khalil J, Barrette K, et al. *Prospective, Randomized, Multi-Center Study of Intraosseous Basivertebral Nerve Ablation for the Treatment of Chronic Low Back Pain (INTRACEPT).* ClinicalTrials.gov Identifier: NCT03246061. [stanfordhe...thcare.org]

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